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KTM
EXAMINER

BLINNER, B

ART UNIT

PAPER NUMBER

1647

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/492.028

Applicant(s)

ZUKER, CHARLES S

Examiner

Art Unit

Bridget E. Bunner

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

MAILING DATE OF THIS COMMUNICATION. ± MONTH(S) FROM

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 December 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) 5 and 9-24 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-4 and 6-8 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claims 1-24 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)
16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4

18) Interview Summary (PTO-413) Paper No(s). _____
19) Notice of Informal Patent Application (PTO-152)
20) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of a method for identifying a compound that modulates sensory signaling in sensory cells comprising contacting the compound with a sensory cell specific G-protein alpha subunit polypeptide and determining a functional effect of the compound upon the polypeptide by binding radiolabeled GTP in Paper No. 10 (22 December 2000) is acknowledged. The traversal is on the ground(s) that claims 1, 4, and 5 are improperly placed in both Groups I and II and that the claims of Groups II and III are classified in the same class with Group III being a subgenus of Group II. Applicant argues that the Examiner has "improperly attempted both to reject these claims for misjoinder, and to reject the claims on the basis that they allegedly represent independent and distinct inventions". This is not found persuasive because no claim rejections were made in the previous restriction requirement (Paper No. 8, 07 November 2000). Further, *In re Weber* 198 USPQ 328 (as cited in Applicant's election, Paper No. 10, 22 December 2000) has a different fact pattern than the instant application. In the case set forth above, the Court reversed the Board's affirmation of the examiner's rejection of specific claims as being improper Markush claims as well as a misjoinder under 35 USC § 121. The Court did not decide an issue regarding restriction under 35 USC §121. *In re Weber* also states that:

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be independent and distinct. *In re Weber* 198 USPQ at 331, 332.

Although the statute allows the Applicant to claim his invention in any manner as he sees fit, the PTO must have some means for controlling such administrative matters as examiner

caseloads and the amount of searching performed. See *In re Weber* 198 USPQ at 332. Also, the restriction requirement and the subsequent action of the examiner in withdrawing non-elected claims from consideration does not constitute a rejection. See *In re Weber* 198 USPQ at 332 and *In re Hengehold* 169 USPQ 473.

Groups I-III as set forth in the previous restriction requirement (Paper No. 8, 07 November 2000) are independent and distinct inventions because they require different ingredients, process steps, and endpoints. Group I requires search and consideration of contacting a compound with a G-protein alpha subunit polypeptide, binding radiolabeled GTP to the polypeptide and measurement of radiolabeled GTP, which is not required by the other inventions. Group II requires search and consideration of coexpression of a G-protein alpha subunit polypeptide (linked to a solid phase) and a sensory cell specific G-protein coupled receptor in a cell (attached to a substrate) and measurement of electrical activity, phosphorylation, transcription levels, and cAMP, cGMP, IP₃, DAG, or Ca²⁺ levels, which is not required by the other inventions. Group III requires search and consideration of coexpression of a G-protein alpha subunit polypeptide and a sensory cell specific G-protein coupled receptor in HEK 293 cells and measurement of intracellular calcium levels, which is not required by the other inventions. Group III is distinct from Group II because a nonoverlapping search is required. The requirement is still deemed proper and is therefore made FINAL.

Claims 5 and 9-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups and non-elected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10 (22 December 2000).

Claims 1-4 and 6-8 are under consideration in the instant application.

Status of Application, Amendments, and/or Claims

The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (Paper No. 6, 05 September 2000) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (mailed on 21 August 2000) are withdrawn.

Specification

1. The disclosure is objected to because of the following informalities:

1a. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pg 20, line 17). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

1b. Two patent applications are referenced throughout the disclosure (pg 4, lines 6-7; pg 11, lines 30-31; pg 32, lines 26-27; pg 59, lines 28-29). The status of the applications must be updated.

Appropriate correction is required.

Claim Objections

2. Claims 1-4 and 6-8 are objected to because of the following informalities:

2a. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Correction of the following is required: The specification does not disclose a detailed description or a working example of a method for identifying a compound that modulates sensory signaling in sensory cells comprising

contacting the compound with G-protein alpha subunit polypeptide and measuring the binding of radiolabeled GTP to the polypeptide.

Appropriate correction is required

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. The term "sensory signaling" in claim 1 is a relative term which renders the claim indefinite. The term "sensory signaling" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what type of signaling the term "sensory signaling" is intended to encompass. G protein subunits are involved in numerous signal transduction events with different ion channels.
5. Claims 1-4 and 6-8 recite identifying a compound that modulates sensory signaling in sensory cells, but the method steps do not achieve the goal in the preamble.
6. Claims 1-4 and 6-8 are vague and indefinite because the claims do not recite what type of binding will occur to be able to identify a compound. For example, will an increase, decrease, or no change in binding of radiolabeled GTP to the G-protein alpha subunit polypeptide identify a compound that modulates sensory signaling?

7. Regarding claim 6, the acronym “GTP” renders the claim vague and indefinite.

Abbreviations should be spelled out in all independent claims for clarity.

8. Claim 6 is indefinite because it is unclear whether open or closed term language is intended. See MPEP § 2111.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freissmuth et al. (Mol Pharmacol 49: 602-611, 1996) in view of Wilkie et al. (Proc Natl Acad Sci USA 88: 10049-10053, 1991). Freissmuth et al. teaches a method for identifying compounds that modulate effects in G proteins comprising contacting the compound with a G protein alpha subunit polypeptide and determining a functional effect of the compound by measuring binding of radiolabeled GTP to the G protein alpha subunit polypeptide. Freissmuth et al. teaches measuring the binding of GTP γ S to recombinant G protein alpha subunits in the presence or absence of adenylyl cyclase and suramin analogues (see pg 603-605 and Figures 2-9).

Freissmuth et al. does not teach the specific G-protein alpha subunit polypeptide comprising the amino acid sequence of SEQ ID NO:2.

Wilkie et al. teaches the G-protein alpha subunit polypeptide comprising the amino acid sequence of SEQ ID NO:2 (see Figure 1A).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of identifying compounds by measuring binding of radiolabeled GTP to a G protein alpha subunit polypeptide as taught by Freissmuth et al. by substituting the Freissmuth et al. G protein alpha subunit with a different G protein alpha subunit (α_{14}) as taught by Wilkie et al.

The person of ordinary skill in the art would have been motivated to make that modification because several specific binding sites exist on the G protein α subunits that may be exploited for the design of synthetic inhibitory or stimulatory ligands. The person of ordinary skill in the art reasonably would have expected success because the method of identifying a compound wherein the compound contacts a G protein subunit and the binding of radiolabeled GTP is measured, or variations thereof, were available and practiced at the time the invention was made. Therefore, the claimed invention as a whole was clearly *prima facie* obvious over the prior art.

Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Strathmann. *Proc Natl Acad Sci USA* 87: 9113-9117, 1990.

Hohenegger et al. *Proc Natl Acad Sci USA* 95: 346-351, 1998.

Cheung et al. *FEBS Letters* 279(2): 277-280, 1991.

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 7:30-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner
Art Unit 1647
February 5, 2001

Elizabeth C. Kummerer

ELIZABETH KEMMERER
PRIMARY EXAMINER